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| 10/580,254 | 12/14/2006 | Fabrizio Dolfi | 290483US0X PCT | 1995 |

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| EXAMINER | |
|---|---|
| JAVANMARD, SAHAR | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1617 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/580,254 | DOLFI ET AL. | |
| | Examiner | Art Unit | |
| | SAHAR JAVANMARD | 1617 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *22 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/6/07; 9/21/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

The Office Action is in response to the 371 of PCT/CA02/01548 filed April 9, 2004. Amended claims 24-55 are being examined on the merits herein.

## Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887,225 USPQ 645 (Fed. Cir. 1985); In re Van Omum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).
A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is Shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 16 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-21 of copending Application No. 10/580,251. Although the conflicting claims are not identical, they are not patentably

distinct from each other because both are drawn to methods of treating rosacea. The instant claims employ "comprising" language and are therefore open to other agents that may also be used to treat rosacea, namely idocilamide.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 12, 13, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Roberts (Drugs of Today, 1987) of record.

Furthermore, no patentable weight is given for the "intended use" of the pharmaceutical composition containing piketoprofen as recited in claims 1-7, 12, 13, and 15. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d

67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Roberts teaches the administration of 1% and 5% piketoprofen applied topically for the treatment of irradiation induced erythema, (page 3, table 1; page 4, column 2, 3rd full paragraph) meeting the limitations of claims 1-7, 12, 13, and 15.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8-10, 14, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arkin (WO 02/074290) of record in view of Waldstricher (US Patent No. 5,543,417).

Arkin teaches a method of treating or preventing rosacea, comprising topical administration, of a pharmaceutical preparation comprising a nonsteroidal anti-inflammatory drug (NSAID) (page 1, 1st paragraph; page 3, 7th full paragraph).

Arkin teaches that NSAIDs are classified according to their chemical structure as follows: Salicylic acid derivatives (e.g., aspirin, sodium salicylate, choline, magnesium trislicylate, salsalate, diflunisal, salicylsalicylic acid, sulfasalazine, olsalazine); para-aminophenol derivatives (e.g., acetaminophen); indole and indole acetic acids (e.g., indomethacin, sulindac, etodolac); aryl acetic acids (e.g., tolmetin, diclofenac, ketorolac); arylpropionic acids (e.g., ibuprofen, naproxen, flubiprofen, ketoprofen, fenoprofen, oxaprozin); anthranilic acids (fenamates) (e.g., mefenamic acid, meclofenamic acid); enolic acids (e.g., oxicams (piroxicam, tenoxicam), pyrazolidinediones (phenylbutazone, oxyphenthratrazone); alkanones (e.g., nabumetone)(page 4).

Arkin teaches that that the NSAID is present in concentrations about 0.1-5% wt of the formulation (page 5, 1st full paragraph).

Additionally, Arkin teaches that additives to such compositions include, but are not limited to, water, surfactants, emulsifiers, diglycerides, triglycerides, stabilizing agents, thickening agents, alpha-hydroxy carboxylic acids, antioxidants, preservatives,

moisturizers, petroleum, mineral oil, glycerol, ethanol, propanol, isopropanol, butanol, polymeric gelling agents, flavoring, colorant and odorant agents and other formulation components, used in the art of pharmaceutical and cosmetic formulary (page 5).

Arkin further teaches that antibacterial agents can also be employed to accompany the NSAID, including the antibacterial agent, metronidazole, which is, by itself, effective in the treatment of rosacea. It is taught that the use of a mixture containing a NSAID and metronidazole is especially preferred since it is believed that such a mixture affords a synergistic effect (page 5- page 6, bridging paragraph).

Arkin does not specifically teach the use of piketoprofen as that NSAID.

As is well know in the art and taught by Waldstreicher, piketoprofen and ketoprofen are both classified as arylpropionic acid derivatives (claim 23, column 106, lines 19-24) and are antiinflammatory agents useful in treating acne (column 6, 18-35).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have employed the composition and method of treatment of rosacea as taught by Arkin and employed piketoprofen as the NSAID. The motivation, provided by Waldstreicher, teaches that both piketoprofen and ketoprofen are arylpropionic acid derivatives useful in treating inflammatory acne conditions. Therefore, it would have been obvious to one in the art, to expect with a reasonable degree of success, that the substitution of one arylpropionic acid derivative for another, namely piketoprofen for ketoprofen, would be equally successful, in the absence of unexpected results.

***Conclusion***

Claims 1-16 are not allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/S. J./

Examiner, Art Unit 1617

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617